

**REMARKS**

It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims remaining in this application be allowed.

**Interview Summary**

The undersigned thanks Examiners Samala and Vu for the courtesies extended during the personal interview conducted on July 27, 2009. The Interview Summary provided by Examiner Samala accurately reflects the discussions held some of which are elaborated upon below.

**Claim Amendments**

Claims 1, 4-8, 10-16 and 24 have been canceled and replaced with new claims 25-30.

Support for these claims is found in the table below:

Claim	Support
25	See, for example, previously presented Claims 1 and Example 1 where ethylene vinyl alcohol copolymer, DMSO and tantalum are employed in combination. In addition, support for the term "up to 40 weight percent" as used to describe the concentration of the polymer is consistent with the teachings of the specification that the upper limit of the polymer is 40 weight percent; finally, the recitation regarding the viscosity of the composition can be found at page 9, paragraph [0042].
26	Previously presented Claim 4.
27	Previously presented Claim 5.
28	Previously presented Claim 7.
29	Previously presented Claim 13
30	Previously presented Claim 24.

Cancellation of Claims 1, 4-8, 10-16 and 24 were made without prejudice to Applicants' filing a continuation application directed to the previously presented subject matter.

No new matter has been introduced by the above amendments and, accordingly, entry of these amendments is requested.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claimed Invention

As discussed during the interview, embolic compositions have been disclosed in the art and typically these compositions comprise a biocompatible polymer such as ethylene vinyl alcohol copolymers, DMSO and a contrast agent. The contrast agent allows the interventional radiologist to monitor delivery of the embolic composition *in vivo*. This is achieved by, for example, including a water insoluble contrast agent such as tantalum in the embolic composition. These compositions are delivered as a liquid with tantalum being held in suspension. Upon contact with blood, the DMSO dissipates resulting in formation of a solid mass containing the polymer and the tantalum. It is this solid mass that acts as the embolus.

When such compositions are so used, the tantalum must meet certain performance criteria. One criteria is that sufficient tantalum be employed in the composition to permit visualization of the embolic composition by the radiologist under fluoroscopic detection means. Another criteria is that the tantalum must be of sufficiently small size so as to remain in suspension during delivery *in vivo*. See, for example, U.S. Patent No. 5,695,480 which discloses embolic compositions comprising tantalum having an average particle size of less than about 10  $\mu\text{m}$ . Still another criteria is that the composition containing such high levels of tantalum maintain adequate flowability through the catheter particularly in high viscosity compositions as now claimed. Yet another criteria is that the tantalum should form a solid coherent mass with the polymer upon contact with blood or other bodily fluid in order to inhibit systemic tantalum distribution. This is necessary to ensure patient health after injection of the embolic composition (e.g., tantalum not encapsulated in the polymer could accumulate in the liver and other organs of the patient).

Heretofore, the art disclosed that the amount of tantalum employed in such embolic compositions could range up to about 40 weight percent although as a practical matter, most of the art employed about 30 weight percent tantalum. Higher concentrations of tantalum raised

concerns about the ability of the polymer to form a coherent mass with all of the tantalum. However, the use of higher concentrations of tantalum would provide enhanced visibility of mass formation *in vivo* to the radiologist. In his declaration of 14 February 2008, Mr. Strauss demonstrated via *in vitro* data the higher clarity of the embolic mass under fluoroscopy when the amount of tantalum used was over 40 weight percent.

However, the reluctance of the art to employ more than 40 weight percent tantalum due to potential adverse event *in vivo* as noted above lead away from its use notwithstanding the potential benefits associated therewith.

This invention is directed to the discovery that the use of contrast agent in excess of 40 weight percent and up to 60 weight percent can be used in embolic composition provided that the composition contains a minimal amount of polymer such that the amount of polymer employed can effectively encapsulate the tantalum. See, for example, paragraph 5 of the Straus declaration, *supra*.

With regard to the above declaration and the data contained in the specification, Applicants now present claims limited to a specific polymer, a specific solvent and a specific contrast agent so that their claims correspond to the proofs provided.

#### **Rejection Under 35 U.S.C. §112, second paragraph**

Claims 1, 4-8, 10-16 and 24 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. As discussed during the interview, the now presented claims obviate this rejection by providing that the concentration of the ethylene vinyl alcohol copolymer is up to 40% which is now consistent with the subsequent recitation of the concentration of the tantalum and the ratio of the polymer to the tantalum.

Withdrawal of this rejection is requested.

#### **Rejection Under 35 U.S.C. §103(a)**

Claims 1, 4-8, 10-16 and 24 stand rejected over Whalen, et al. (US 2002/00909339 – ‘339 application) in view of Patterson, et al. (US 2004/0224864 – ‘864 application) or Porter, et al. (US 2004/0197302 – ‘302 application). For the following reasons, this rejection is traversed.

Initially, Applicants incorporate by reference the arguments heretofore made regarding the '339 application and maintain that this reference does not teach or suggest the claimed invention. Suffice it to note that Whalen, et al. fail to disclose the use of contrast agent in the amounts recited herein coupled with the ratio of polymer (ethylene vinyl alcohol copolymer) to contrast agent (tantalum) as now required in the claimed invention. Nor does Whalen suggest any benefit that could be achieved by such a combination of contrast agent and polymer.

As to the '864 and the '302 application, Applicants maintained during the interview and maintain now that they are unrelated art to the '339 application as well as to the now claimed invention which excludes their teachings by virtue of the transitional language "consisting essentially of". Specifically, the '339 application does not recite the inclusion of a thixotropic agent in the embolic composition. Rather, the disclosure therein recites that the high viscosity embolic composition has a viscosity of at least about 150 cSt at 40°C.

Contrarily, both the '864 and the '302 applications recite the inclusion of a thixotropic agent into a high viscosity embolic composition which reduces the viscosity of the composition under shear. As the Examiner is well aware, the transitional language "consisting essentially of" excludes from the claims any material which materially affects the characteristics of the invention. The use of a thixotropic agent reduces the viscosity of the composition during shear and the viscosity of the composition is part of the invention of the '339 application as well as a recitation in the now claimed invention. As such, Applicants maintain that both the '864 and the '302 applications are unrelated art as compared to the '339 application as they relate to the now claimed invention.

Withdrawal of this rejection is requested.

Obviousness-Type Double Patenting Rejection

Claims 1, 4-8, 10-16 stand rejected under the judicially created doctrine of obviousness-type double patenting over Claims 1-6 of U.S. Patent No. 5,667,767 (the '767 patent) and Claims 1-8 and 16-23 of U.S. Patent No. 5,695,480. For the following reasons, this rejection is traversed.

Initially, Applicants note that the relied upon claims in both patents were cited for their teaching of polymers such as polyvinylacetate, cellulose acetate butyrate, nitrocellulose and copolymers of urethane/carbonate and styrene /maleate. As the now claimed invention is directed only to ethylene vinyl alcohol copolymers, any such recitation is not material to the now claimed invention.

Notwithstanding the above and for the record, the '767 patent is directed to ethylene vinyl alcohol copolymers in combination with DMSO (Claim 3) and tantalum (Claim 4). Nevertheless, the '767 patent fails to disclose high viscosity compositions such as those now claimed nor does it disclose the use of tantalum in excess of 40 weight percent in combination with a ratio of ethylene vinyl alcohol copolymer to tantalum of greater than 0.07 when using such high levels of tantalum.

As to the '480 patent, this patent recites that the water insoluble contrast agent has an average particle size of about 10 microns or less. Claim 3 of that patent recites that the solvent is DMSO. Claim 5 recites that the water insoluble contrast agent is tantalum and Claim 14 recites that the polymer is an ethylene vinyl alcohol copolymer. As with the '767 patent, the '480 patent fails to disclose high viscosity compositions such as those now claimed nor does it disclose the use of tantalum in excess of 40 weight percent in combination with a ratio of ethylene vinyl alcohol copolymer to tantalum of greater than 0.07 when using such high levels of tantalum.

In view of the above, this rejection is in error. Withdrawal of this rejection is requested.

### **Conclusion**

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-4972. Should no proper payment be enclosed herewith, as by the credit

card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-4972. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-4972.

Respectfully submitted,

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By Gerald F. Swiss

SWISS TANNER, P.C.  
Customer Number: 88984  
Telephone: (650) 305-2699  
Facsimile: (650) 949-2065

Gerald F. Swiss  
Attorney for Applicant  
Registration No. 30,113